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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/847,046	04/30/2001	Peter Hevezi	A-69199-1/DJB/JJD	5223

7590 10/20/2004

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EXAMINER

DAVIS, MINH TAM B

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/847,046

Applicant(s)

HEVEZI ET AL.

Examiner

MINH-TAM DAVIS

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) 1-6, 8-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7 and 40-44 is/are rejected.
- 7) ☒ Claim(s) 39 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The finality of the previous Office action has been withdrawn, and the prosecution of this application is reopened to include art not previously cited.

Accordingly claims 7, 39-44 are examined in the instant application.

OBJECTION

1. Claim 39 appears to be free of prior art but is objected to as being dependent upon a rejected base claims, but would be allowable if rewritten in independent forms, including all of the limitations of the base claim.
2. Claim 40 is objected to because claim 40 does not further limit claims 7 and 39.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, SCOPE, NEW REJECTION

Claims 7, 40-44 are rejected under 35 USC 112, first paragraph, because the specification, while being enabling for a method for detecting prostate cancer, comprising detecting an increased mRNA level of SEQ ID NO:1, is not enabled for a method for detecting prostate cancer, comprising detecting an increased mRNA level of a DNA "encoding an amino acid sequence of SEQ ID NO:2".

Claims 7, 40-44 are drawn to a method for diagnosing prostate cancer, comprising determining the mRNA expression level of a gene encoding an amino acid sequence of SEQ ID NO:2 in prostate tissue, wherein an increased level of mRNA

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expression indicates prostate cancer, and wherein said mRNA expression is measured using a nucleic acid probe completely complementary to SEQ ID NO:1.

The specification discloses one isolated PAA3 polynucleotide, SEQ ID NO:1, which is detected to have higher level of expression in prostate cancer as compared to normal tissues and normal prostate tissue, using oligonucleotide microarrays interrogated with cRNAs from prostate cancer tissues or normal tissues including normal prostate tissues. Said cRNAs are generated by *in vitro* transcription (IVT) from cDNA synthesized from mRNAs isolated from the above tissues and then hybridize to oligonucleotide arrays. The specification further discloses that a nucleic acid having the sequence shown in accession No:AA609723 is used as a probe on the biochips (Example 1 on pages 60- 66, Example 3 on pages 69-70).

One cannot extrapolate the teaching in the specification to the scope of the claims. One can extrapolate from a single species of mRNA, SEQ ID NO:1, which is overexpressed in prostate cancer tissue as compared to normal prostate tissue to a whole universe of degenerate sequences of SEQ ID NO:1, the overexpression of which is not predictable, in view that one cannot predict that the claimed degenerate sequences would have the same promoter or enhancers as the sequence comprising SEQ ID NO:1, and that there is no guidance of which degenerate sequences of SEQ ID NO:1 are overexpressed in prostate cancer tissue as compared to normal tissue.

Since one cannot predict whether the claimed degenerate sequences would be overexpressed in prostate cancer tissue as compared to normal tissue, one would not

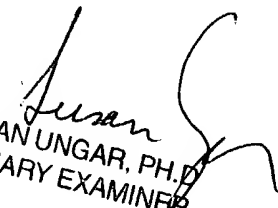
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know how to use the claimed sequences encoding the amino acid sequence of SEQ ID NO:2.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JEFFREY SIEW can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


SUSAN UNGAR, PH.D.
PRIMARY EXAMINER

MINH TAM DAVIS

October 10, 2004

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